XI. **510(k) Summary**

Submitter: Dr. Eugenio Miceli, QA Manager, Micerium SpA, Via Marconi, 83, 16030 Avegno (GE), Italy. Phone: 39 0185 7887 870.

I. Classification Name and Number: endosseous Implant (DZE),

II. Common/Usual Name: Dental implant, Orthodontic implant

III. Proprietary Name: Miniscrews Anchoring System™, (MAS™ System)

IV. Registration No.: Foreign, in process

V. Compliance with Performance Standards: No performance standards are applicable. Followed guidance document, "Class II Special Controls Guidance Document: Root-form Endosseous Implants ....", May 12, 2004.

VI. Description of the Device: This device is an endosseous dental implant consisting of the major component, of root-form, screw type, and the accessories, designed to facilitate placing and using the implant in orthodontic procedures. The accessories contact tissue for less than 1 hour and therefore are exempt from 510(k) requirements and are described only generally. The smoothly curved head has a groove in the middle for the attachment of elastics, chains, or coil springs commonly used in orthodontics. The head (groove) has a aperture where a wire or auxiliary can be attached. The rounded head of the implant has an internal hexagon for insertion of the screw driver. The MAS implant is made from Group V titanium.

VII. Labels and Labeling: Draft labels of the MAS™ system and instructions for use are provided.

VIII. Substantial Equivalence: The MAS™ system is substantially equivalent to several small implant systems currently on the market. A list of these is provided, and includes: Orlus Mini Screw, cleared by the Orthолution Co., LTD, in K050568; Tomas Pin, cleared by Dentaurum, Inc., in K042965; Dual Top Anchor System Screws, cleared by Jeil Medical Corp., in K033767; Ostemed Orthodontic Screw System, cleared by OsteoMed, LP in K0312936; Implant Orthodontic Anchor System, cleared by Nobel Biocare USA, Inc. in K000643.

The implant is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use as predicate devices, intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth.

2. The technological characteristics for this product are similar to those of the predicate devices and those currently on the market They are screw-type endosseous dental implants with design and manufacturing concepts and materials very similar to those of the predicate devices. Like the Jeil Medical Dual Top system, they have a rounded head with a groove around it for the attachment of elastics, chains or coil springs. Like the Thomas Pin implant, the MAS™ system implants are made of Grade V titanium, are solid, one-piece, self-tapping implants with a roughened screw area for rapid osseointegration and a transmucosal neck that has a smoothly machined surface to allow the ready attachment of epithelial tissue

3. Descriptive information provided shows that the materials from which this device is made are well-established and well understood in the industry and among professional users. The material (titanium, Grade V) is identical to some of the implants, and similar to those of the others common in industry.

4. The FDA "Decision-Making Process" chart was used and appears in Appendix V.

IX. Potential Adverse Effects and Complications: (Common to all devices of this type)

- Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking, or fracture of the device or premature losss of fixation with bone, leading to non-union.
- Migration, bending, fracture or loosening of the implant.
- Metal sensitivity or allergic reaction to a foreign body.
- Pain, discomfort or abnormal sensation, due to the presence of the device.
- Increased fibrous tissue response around the fracture site and/or the implant.
- Necrosis of bone.
- Inadequate healing.

Apart from these adverse effects there are always possible complications of any surgical procudure such as, but not limited to, infection, nerve damage, and pain which may not be related to the implant.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 8 2006

Mr. Eugenio Miceli
Quality Assurance Assistant
Micerium S.pA.
Via Marconi 83
Avengo, Italy 16030

Re: K062367
Trade/Device Name: Miniscrews Anchoring System, M.A.S.™ Implants
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: November 29, 2006
Received: December 4, 2006

Dear Mr. Micali:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IX. Indications for Use [Separate Page]

510(k) Number: (not assigned)

Device Name: M.A.S.™ implants

Indications for Use:

This device is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only on adults over the age of 12.

Prescription Use X or Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K062367